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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,457	11/29/2000	Meir Shinitzky	24390	6935
20529	7590	09/12/2005	EXAMINER	
NATH & ASSOCIATES 1030 15th STREET, NW 6TH FLOOR WASHINGTON, DC 20005			TURNER, SHARON L	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*ML*

**Office Action Summary**

Application No.

09/647,457

Applicant(s)

SHINITZKY ET AL.

Examiner

Sharon L. Turner

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-31 is/are pending in the application.
- 4a) Of the above claim(s) 20-26, 28, 30 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 and 29 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 15-19 is/are objected to.
- 8) ☒ Claim(s) 15-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Response to Amendment**

1. The Art Unit of U.S. Patent application No. 09/647,457 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1649.
2. The amendment filed 6-24-05 has been entered into the record and has been fully considered.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
4. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn.
5. Claims 1-14 are canceled. Newly presented claims 15-31 are pending.

***Election/Restriction***

6. Applicant's previous election with traverse of Group I, claims 1-6, 8, 10-11 and 13-14 in part to the extent drawn to the technical feature of SEQ ID NO:2 in Paper No. 10 (4-29-02) is acknowledged. The traversal is on the ground(s) that there is no appropriate explanation of serious burden. Applicants submit that there is no serious burden because a search of any one of the inventions would require searching areas appropriate to the other inventions and further because Applicants would be forced to pay further fees for search and examination of the additional inventions. This is not found persuasive because as previously set forth the technical features differ in sequence structure, function, effects and are capable of distinct utilities. There is extensive search burden in examining all the inventions in a single application because

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the search for any one group is not co-extensive with a search for any other group, in particular the sequence searches are different for each invention. The fee structure has been determined by the Office to be appropriate compensation for the burden of search and examination of alternative inventions.

The requirement is still deemed proper and is therefore made FINAL.

7. It is noted for the record that the amendment of 6-24-05 presents new CRF and paper copies of a sequence listing. The sequences as presented 6-24-05 differ substantially from those as originally filed.

8. Newly amended claim 15 is directed to a new genus as defined in claim 15. The new sequence identifier of SEQ ID NO:1 and noted generic sequence of claim 15 are asserted to be directed to the elected invention as new SEQ ID NO:1 is deemed to be generic to previously presented and elected SEQ ID NO:3, noted to be presented as SEQ ID NO:2 as originally filed. However, the newly generic sequence is not apparently supported within the specification as originally filed or as amended in the CRF and paper copy of the sequence listing submitted 6-24-05 as the scope of the sequences and definitions of Xaa residues as set forth in the paper copy of the sequence listing do not correspond to the definitions denoted within the specification as originally filed. In particular p. 9 is noted for support. However the scope of the sequences presented therein differ from the newly recited genus. The first and third definition of Xaa1 contradict, and further the sequences of SEQ ID NO's:2 and 4-7 do not correspond to the formula. Accordingly, search is not linking and has not been expanded over instant SEQ ID NO:1 and previously searched SEQ ID NO:3.

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9. Newly submitted claims 20-26, 28 and 30-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are directed in part to non-elected inventions directed to alternative sequence identifiers, to kits comprised of antibodies and to assays.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-26, 28 and 30-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Sequence Compliance***

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth herein. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

In particular, claim 1 denotes particular limitations to the Xaa residues as in SEQ ID NO:1. However, these limitations are not in agreement with the notations within the computer readable format and paper copy of the sequence listing and accordingly the application is not in compliance with the sequence rules.

Correction of the computer readable format and paper copy of the sequence listing is required.

For example SEQ ID NO:2 and 4-7 are not in correspondence with the formula of SEQ ID NO:1, in particular the sequence designates Ala, Pro rather than Pro, Ala as required. Moreover the first and third definition of Xaa1 contradict each other. Such must be rectified.

### ***Claim Objections***

11. Claims 15-19 are objected to as being drawn in part to non-elected inventions,

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(as reciting an improper Markush Group and/or inventions that are non-linking).

M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

In particular it is noted that the additional sequences (SEQ IDNO's 2 and 4-7) within claims 18 and 19 lack unity of a common core structure designated as SEQ ID NO:1 and thus remain drawn to non-elected inventions. SEQ ID NO:1 is apparently generic to SEQ ID NO:3, 8 and 9. However, the generic sequence is noted to have problems with the contradictory limitations to Xaa1 and thus definitive designation is impossible.

12. Claims 15-19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As previously noted SEQ ID NO:1 is not apparently generic to SEQ ID NO:2 and 4-7 and further the designation of Xaa1 is contradictory and the scope of its definition must be resolved.

### ***Specification***

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13. The amendments filed 6-24-05 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Those changes that are newly drawn to a generic sequence represented as new SEQ ID NO:1 within the sequence listing. The scope of the sequences represented is not apparently supported by the specification as originally filed. SEQ ID NO:1 is not described within the specification as it is newly set forth in the sequence listing and does not correlate with the claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicants traverse in the 6-24-05 response stating that the offending subject matter is not delineated.

Applicants arguments have been fully considered but are not persuasive. As noted it is the scope of the CRF and paper copy of the sequence listing that are not apparently supported. While the paper and CRF copy have been amended, the problems remain in that the scope of the sequences encompassed is broader and not supported by p. 9, or otherwise as originally filed. Rejection is maintained over the newly filed paper and CRF format.

***Claim Rejections - 35 USC § 112***

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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15. Claims 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants present newly claimed generic SEQ ID NO:1 as set forth in claim 15 and the newly submitted sequence listing of 16-24-05. Applicants point to support for the amendments at pp. 9 of the specification and within the originally filed SEQ ID NO's:2, 7 and 8. However, support for the new recitations as generically recited are not found and moreover the limitations do not apparently correspond. In particular, new sequences, 2 and 4-7 are not generic to SEQ ID NO:1. Also, within the scope of SEQ ID NO:1, the limitations of Xaa1 contradict. At one point it is specified that if it is C, G or P then Xaa2 is absent or R but then it stipulates if it is G or P then Xaa2 comprises R. Clarification and direct support is required for the full scope of the sequences. Accordingly the recitations constitute new matter absent evidence for support within the full scope from the specification as originally filed.

#### ***Status of Claims***

16. Claim 27 and 29 are allowed.

#### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

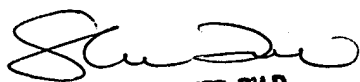
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached at (571) 272-0867.

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Sharon L. Turner, Ph.D.  
September 6, 2005

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
9-6-05